UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,759	11/04/2005	Franz Feiner	P0777.70001US00	1325

23628 7590 02/02/2010

WOLF GREENFIELD & SACKS, P.C.
600 ATLANTIC AVENUE
BOSTON, MA 02210-2206

EXAMINER	
OSTRUP, CLINTON T	
ART UNIT	PAPER NUMBER
3771	
MAIL DATE	DELIVERY MODE
02/02/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,759	FEINER ET AL.	
	Examiner	Art Unit	
	CLINTON OSTRUP	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date ____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 3, 2009 has been entered.

2. As directed by the amendment, claims 1-6, 9-10, 17, and 20 have been amended. No claims have been cancelled and no new claims have been added; thus, claims 1-20 are pending in this application.

Claim Objections

3. Claims 1-20 are objected to because of the following informalities: Claims 1 & 20 are objected to as containing multiple periods. Each claim must begin with a capital letter and end with a period. Periods may not be used elsewhere in the claims except for abbreviations. See: *Fressola v. Manbeck*, 36 USPQ2d 1211 (D.D.C. 1995). See: MPEP 608.01(m). Any remaining claims are objected to as depending from an objected base claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sommer et al. (WO 01/85241A1), based on the machine translation provided by the European Patent Office, and further in view of Danby et al., (5,680,111).

Regarding claims 1 & 20, Sommer discloses a nebulizer device (figure 1) for detecting the parameters of an aerosol (flow) comprising a transmitting means (7) which is disposed on a body (5) that at least partially surrounds an aerosol area (inside mouthpiece), and which emits radiation (infrared light) into said aerosol area through a transparent material disposed between the transmitting means and aerosol area; a first receiving means (8), which is disposed on the body (5) that at least partially surrounds said aerosol area (inside mouthpiece), which is disposed in relation to said transmitting means (7) so as to primarily receive transmission radiation (infrared light) that passes through the aerosol area, and which emits a first analysis signal (output signal of 8) that corresponds to the intensity of the received transmission radiation; and a control means (9), to which the output signals (via 8) are supplied and which analyses the output signals in order to determine the parameters (flow) of an aerosol in said aerosol area. See: figures 1-3 & 12.

However, Sommer lacks the specific teaching that the droplets from the aerosol adhere to the body in an area through which the radiation is transmitted from the transmitting means into the aerosol area so that the transmitted radiation passes through the aerosol area in an unscattered manner and a second receiving means disposed on the body that at least partially surrounds the aerosol area; which is

disposed in relation to said transmitting means so as to primarily receive scattered radiation and which emits a second analysis signal that corresponds to the intensity of the received scattered radiation. Sommer also lacks the specific teaching that the droplets from the aerosol adhere to the body in an area through which the radiation is transmitted from the transmitting means into the aerosol area

Danby et al. teaches a device for detecting air in a tubular system that uses a transmitter with two receivers and describes how the system works well with transparent or translucent tubes. Danby teaches how the one receiver is at a ninety degree angle in relation to the transmitter and the other receiver is at a one hundred and eighty degree angle in relation to the transmitter. Danby teaches that both receivers are connected to a processor which processes the light receivers' outputs to detect air in the tubing. See: abstract, col. 3, lines 28-54; col. 4, line 58 - col. 5, line 6 and figures 3 & 8.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the nebulizer flow transmission and detection device disclosed by Sommer by utilizing a pair of sensors disposed perpendicular to each other, as taught by Danby, in order to provide a nebulizer flow detector with increased precision.

Regarding the use of a transmitting means which emits radiation into an aerosol area through a translucent material, Danby contemplates using both transparent and translucent materials. Regarding the droplets from the aerosol adhering to the body in an area through which the radiation is transmitted from the transmitting means into the aerosol area, it is the examiners position that the device disclosed by Sommer, which

utilizes a body (5) in an area (near mouthpiece) through which the radiation (from 7) is transmitted from the transmitting means (7) into the aerosol area (inside 5) and the droplets from the aerosol would be expected to contact the inner walls of the mouthpiece and adhere thereto.

Regarding claim 2, the combined references teach a translucent material (Danby) which is a tube that surrounds the aerosol area (inside mouthpiece of Sommer).

Regarding claim 3, the combined references teach a first receiving means (20b of Danby) receives the transmission radiation through a second wall section (adjacent 20b) of the body (5 of Sommer) surrounding the aerosol area (inside mouthpiece of Sommer.

Regarding claim 4, the combined references teach a second receiving means (20a of Danby) that receives the scattered radiation (infrared light) through a third wall section (adjacent 20a) of the body (5 of Sommer) surrounding the aerosol area (inside mouthpiece of Sommer).

Regarding claim 5, the combined references teach a body (5 of Sommer) surrounding the aerosol area (inside mouthpiece of Sommer) and Danby teaches a transparent or translucent material can be used. See: See: col. 1, line 65 - col. 2, line 13 & abstract of Danby.

Regarding claim 6, the combined references teach a body (5 of Sommer) surrounding the aerosol area (inside mouthpiece of Sommer) is made of a transparent material and Danby teaches a transmitting means (21 of Danby), that functions well

whether it is made of a transparent or a translucent material, through which radiation is emitted. See: col. 1, line 65 - col. 2, line 13 & abstract of Danby.

Regarding claim 7, the Danby teaches a first receiving means (20b of Danby) and teaches that the device works reliably well using transparent of translucent materials, thus it would be obvious to provide a surface made of a translucent material, through which the radiation is received because the system provides reliable detection of air bubbles through both transparent and translucent materials.

Regarding claim 8, Danby teaches a second receiving means (20a of Danby) and teaches that the device works reliably well using transparent of translucent materials, thus it would be obvious to provide a surface made of a translucent material, through which the radiation is received because the system provides reliable detection of air bubbles through both transparent and translucent materials.

Regarding claim 9, Sommer discloses a control means (9) that activates the transmitting means to emit the radiation into the aerosol area (inside mouthpiece of Sommer).

Regarding claim 10, Sommer discloses a control means (9) that activates the transmitting means (7) such that first time periods in which the transmitting means emits radiation (infrared light) into the aerosol area (inside mouthpiece of Sommer), alternate with second time periods (when not in use) in which the transmitting means (7 does not emit radiation into the aerosol area (inside mouthpiece).

Regarding claim 11, when the transmitter (7 of Sommer) is not transmitting light, it is reasonably expected that during this (not in use) second time period the control

means (9 of Sommer) determines the proportion of ambient light in the output signals (as ambient light is the only light being received by the receiver when the transmitter is not transmitting) of the first (20b of Darby) and/or second (20a or Darby) receiving means.

Regarding claim 12, since ambient light is present when the receivers are receiving the infrared light, it is reasonably expected that the control means (9 of Sommer) which receives signals from the receivers, would make use of the proportion of ambient light (the amount of ambient light sensed in combination with the amount of light received by the transmitter) when analyzing the output signals of the first and second receiving means (20b & 20a of Darby).

Regarding claim 13, Sommer discloses a control means (9) that is capable of determining the difference of the output signal of the first receiving means (20b) and the first ambient light proportion (portion of ambient light surrounding 20b prior to the transmitter transmitting infrared light) and/or the difference of the output signal of the second receiving means (20a) and the second ambient light proportion (ambient light surrounding 20a prior to the transmitter transmitting infrared light).

Regarding claim 14, Sommer discloses a control means (9) that is capable of forming a quotient from the difference of the output signal of the second receiving means (20a) and the second ambient light proportion (ambient light surrounding 20a prior to the transmitter transmitting infrared light) and the difference of the output signal of the first receiving means (20b) and the first ambient light proportion (ambient light surrounding 20b prior to the transmitter transmitting infrared light).

Regarding claim 15, Sommer discloses a control means (9) that is capable of forming a quotient from the output signal of the second receiving means (20a) and the output signal of the first receiving means (20b) and it would be obvious to one having ordinary skill in the art to form a quotient in order to determine the signal strength coming from each receiver to the controller.

Regarding claim 16, Sommer discloses infrared light as the radiation emitted by the transmitting means (7).

Regarding claim 17, Sommer discloses a body (5) surrounding the aerosol area (inside mouthpiece) that is a mouthpiece (5) for an inhalation therapy device.

Regarding claim 18, Sommer discloses nebulizer devices with a nebulizer nozzle (40 of figure 1) and a membrane nebulizer (52 of figure 12).

Regarding claim 19, Sommer discloses the control means (9) is connected with a compressor (2) for the nebulizer nozzle (40 of figure 1) or with an excitation device (56 of figure 12) for the membrane (52) nebulizer.

Response to Arguments

6. Applicant's arguments filed November 3, 2009 have been fully considered but they are not persuasive.

7. Applicants argue on page 8, first full paragraph, that Sommer lacks a first receiving means disposed in relation to the transmitting means so as to primarily receive transmission radiation that passes through the aerosol area in an unscattered manner, the examiner respectfully agrees. However, the rejection was based upon the combined teachings of Sommer and Danby.

One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Danby was specifically used to teach a system that uses a transmitter with two receivers and how the system works well with transparent or translucent tubes.

Applicant then argues on page 8, third full paragraph, that Danby does not teach detection of aerosol parameters and thus cannot teach how to obtain improved results in detecting aerosol parameters, as Danby teaches a sensor for detecting air bubbles in a liquid. The examiner respectfully disagrees.

First, the examiner has merely suggested the placement of the infrared transmitter and sensors (receivers) of Sommer be placed in the same configuration as described by Danby and using a translucent tube, as suggested by Danby. Since translucent plastics are commonly used and well known in the art to be used with infrared transmitters and receivers, as these plastics are transparent to infrared light while being translucent to visible light, the suggestion by Danby to use either transparent or translucent materials logically flows from a common sense reading of the combined references.

Regarding applicant's assertion on page 9, second full paragraph that they have discovered translucent material disposed between the transmitting device and the aerosols area provides improved results with respect to a transparent tube in detecting aerosol parameters, applicants have not provided any objective evidence to support the

translucent properties of the tube as having improved detection of aerosol parameters, but even if such evidence was provided, Danby clearly suggests the use of both transparent and translucent tubes.

Regarding applicant's argument on page 9, last paragraph, that the specific sensor output of Danby differs for that of the sensor output used in the present invention, applicant is reminded that these features are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Moreover, Sommer was used for the specific sensor outputs and Danby was used for the sensor orientation to improve the sensed parameters of Sommer.

8. Applicant essentially argues on page 10, that claims 2-20 are patentable over the prior art for the same reasons that claim 1 should be allowed. However, as discussed above, claim 1 is obvious over the combined teachings of Sommer and Danby and therefore the rejection has been MAINTAINED.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mudge et al. (4,447,726) is being used as a teaching reference to show that infrared sensors commonly use translucent materials between the sensor and the object being sensed. Galvin et al (4,321,594) is being provided as a teaching reference to show translucent plastics are well known in the art to discriminate between

visible light sand infrared light. Yagita (2002/0063215) teaches detecting impurities in liquids bottled in transparent or translucent containers using IR and X-rays.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771